

REMARKS

Finality of the Office Action

As discussed during the telephonic interview, Applicants submit that the Office Action mailed January 28, 2009 should not have been final. In particular, Applicants note that the current Office Action cites Angell et al., which was not cited in previous Office Actions. Applicants note that the Response to the previous Office Action submitted December 29, 2008 did not introduce any claim amendments. Accordingly, in view of the fact that the citation of Angell et al. was not necessitated by Applicants' amendment, Applicants maintain that the current Office Action should not have been made final.

Applicants thank the Examiner for her voice-mail of March 26, 2009 agreeing to withdraw the finality of the Office Action.

Rejections Under 35 U.S.C. §103

Claims 21-23, 28, and 31-35 stand rejected on the assertion that they are obvious over Moe et al. (U.S. Patent Publication 2003/0023302) and Angell et al. (U.S. Patent No. 3,983,581). In particular, the Examiner asserts that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Moe et al. to include a porcine valve as described in Angell et al.

The Examiner must consider all the limitations recited in the claims when determining whether the claimed invention is obvious. (See M.P.E.P. §2143.03; See also *In re Royka*, 180 USPQ 580 (CCPA 1974) providing that in order for a claimed invention to be obvious all the claim features must be taught or suggested by the prior art). As discussed in the telephonic interview, Applicants maintain that the combination of Moe et al. and Angell et al. does not teach or suggest all the elements of the claimed invention. In particular, this combination of references does not teach or suggest a biological prosthesis comprising at least one intraparietal reinforcement device comprising a rod implanted in said tubular outer wall of an aortic valve, the rod penetrating the thickness of the tubular outer wall of the aortic valve. As noted in the Response to the previous Office Action submitted December 29, 2008 and discussed during the telephonic interview, the stents 16 (and tabs 13) of the Moe et al. reference are not implanted in the valve body 12 but rather are placed in a space between two layers of the polymer (see

Fig. 1 A depicting tabs 13 positioned in a space between two layers of the polymeric valve body 12). Thus, Moe et al. does not disclose “a rod penetrating the thickness of the tubular outer wall of the aortic valve” as recited in the currently pending claims.

Similarly, in Angell et al., the frame struts 24, 25, 26 do not penetrate the tissue. Rather, the valve is sutured along the interior surface of the frame. (See Angell et al., Column 5, lines 30-46).

Accordingly, because the combination of Moe et al. and Angell et al. does not teach or suggest prostheses comprising a rod penetrating the thickness of the tubular outer wall of the aortic valve as recited in the currently pending claims, the claims cannot be obvious over the cited combination of references.

Furthermore, Applicants submitted a Declaration by Dr. Norman Jaffe on December 29, 2008 attesting that, if the device of Moe et al. was combined with the porcine valve described in Angell et al., the device would be expected to fail. (See Declaration at Paragraph 8). In response, the Examiner asserts that the Declaration is moot in view of the citation of Angell et al. and that “implants are not chosen solely based on life expectancy as an implant lasting 1-2 years may serve a particular patient’s need. And as evidenced by Gupta above, coatings are known to provide enhanced durability. Furthermore, the evidence of the Declaration is based on opinion and appears to suggest the device would not work well rather than would not work at all.” (Office Action at page 4).

Applicants maintain that the Declaration is not moot and note that the Examiner must consider the evidence presented in the Declaration. *In re Alton*, 37 USPQ2D 1578 (CAFC 1996). As discussed during the telephonic interview, the Examiner has not provided any basis for her assertions that the device resulting from the combination of Moe et al. and Angell et al. would be expected to last 1-2 years nor has she provided any basis for her assertion that an implant lasting 1-2 years may serve a particular patient’s needs. In fact, Applicants submit that it would not be practical to subject a patient to repeated surgeries every 1-2 years in order to replace valves with short lifetimes. In this regard, Applicants note that ISO 5840 requires that the durability of biological valves must be tested over 200 million cycles and the durability of mechanical valves must be tested over 500 million cycles. As 200 million cycles represents approximately 5 years, a valve that lasts only 1-2 years would clearly be unacceptable.

As also discussed during the telephonic interview, because one of skill in the art would expect a device resulting from the combination of Moe et al. and Angell et al. to fail, one skilled in the art would not make such a combination. Applicants note that during the telephonic interview it was concluded that, pending further review, this aspect of the Declaration appeared to be strong evidence that the claimed invention is not obvious over the combination of Moe et al. and Angell et al.

For the foregoing reasons, Applicants submit that Claims 21-23, 28, and 31-35 are not obvious over Moe et al. in combination with Angell et al.

Claims 24-26 were rejected on the assertion that they are obvious over Moe et al. in view of Angell et al. further in view of Rosen (U.S. Patent No. 4,345,340). Rosen is cited as teaching a heart valve with commissure points. As Rosen does not cure the deficiencies discussed above with respect to Moe et al. and Angell et al., Applicants maintain that Claims 24-26 are not obvious over the cited combination of references.

Claim 27 was rejected on the assertion that it is obvious over Moe et al. in view of Angell et al. further in view of Gupta (U.S. Patent No. 4,851,000). Gupta is cited as teaching heart valves coated with a fluoropolymer. As Gupta does not cure the deficiencies discussed above with respect to Moe et al. and Angell et al., Applicants maintain that Claim 27 is not obvious over the cited combination of references.

Claims 29-30 were rejected on the assertion that they are obvious over Moe et al. in view of Angell et al. further in view of Pavcnik (U.S. Publication No. 2001/0039450). Pavcnik is cited as teaching an implantable valve with an intraparietal reinforcement device having helical shapes. In contrast to the Examiner's position, Pavcnik does not teach or suggest a biological prosthesis comprising at least one intraparietal reinforcement device comprising a rod implanted in said tubular outer wall of an aortic valve obtained from an animal, the rod penetrating the thickness of the tubular outer wall of the aortic valve. In particular, the expandable frame described in Pavcnik does not contain rods which penetrate the tubular outer wall of an aortic valve obtained from an animal. As Pavcnik does not cure the deficiencies discussed above with respect to Moe et al. and Angell et al., Applicants maintain that Claims 29-30 are not obvious over the cited combination of references.

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No Disclaimers or Disavowals

Any remarks in support of patentability of one claim should not be imputed to any other claim in this or a related application, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on solely that portion; rather, patentability must rest on each claim taken as a whole.

Although changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter. In particular, although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
11/814,155	INTRAPARIETAL REINFORCING DEVICE FOR BIOLOGICAL CARDIAC PROSTHESIS AND REINFORCED BIOLOGICAL HEART VALVE PROSTHESIS	July 17, 2007
11/775,043	REINFORCEMENT DEVICE FOR A BIOLOGICAL VALVE AND REINFORCED BIOLOGICAL VALVE	July 9, 2007

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Conclusion

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

The undersigned has made a good faith effort to respond to all of the noted rejections and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if an issue requires clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve any such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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